Technical White Paper

X-Link Bedside Multi-modal Connectivity Technology

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1 Context

1.1 Clinical Data Informatization

Modern clinical diagnosis and treatment plans are based on clinical guidelines and standardized procedures, which are formulated through the accumulation of long-term clinical case data and scientific research and analysis. Similarly, the physician's judgment on the clinical condition of a patient is also based on multi-dimensional diagnosis and treatment data as well as continuous analysis of the clinical course, so as to continuously formulate the optimal clinical treatment plan. Therefore, clinical informatization of patient data, especially the acquisition, integration, analysis, storage, and convenient sharing of clinical data, will be essential for the modern IT infrastructure of hospitals.

Informatization is particularly important for emergency and critical departments. For routine bedside diagnosis and treatment, informatization enables the exchange of data and integrates various types of data. Bedside data such as ventilator and infusion pump data is consolidated on a unified monitor data platform. Outside the ward, a nursing system can be built on a central monitoring system (CMS) to automatically transmit data, allowing the physician to browse the vital sign data and alarms (event review) of the patient in the ward from the CMS, workstation, viewing station, and other clients. In this way, the physician can observe the medication effect in real time, know the patient's real-time condition, judge the prognosis of the clinical condition, and provide the optimal diagnosis and treatment plan. All of this depends on high management efficiency of patient data in emergency and critical departments.

1.2 Characteristics of Bedside POC Ultrasound

In recent years, the clinical value of bedside point-of-care (POC) ultrasound in clinical departments represented by intensive care units (ICUs) has been widely recognized. In ICUs, bedside ultrasound can not only be used for clinical condition assessment and detection of issues in a timely manner, but also for multi-target, integrated, dynamic evaluation, which can acquire important data together with other monitoring methods, and provide prompt and accurate guidance for diagnosis and treatment adjustments.

However, ultrasound equipment is currently an information silo in bedside equipment and has not yet been integrated into the bedside information network. Before ultrasound is used, ultrasound equipment cannot conveniently retrieve existing patient information from the bedside information network, so the patient information must be manually input for management purposes. When ultrasound is used, ultrasound evaluation sometimes needs physiological signal waveforms for quantitative analysis, which requires the physician to disconnect the patient-connected lead wire from the patient monitor and reconnect it to the ECG module of ultrasound equipment. This is time-consuming and laborious, making cable management difficult. After ultrasound is used, ultrasound images cannot be exported quickly and conveniently or directly input to the CMS. This makes it difficult for ICU physicians to conduct multimodal information integration and system analysis. The current situation of POC ultrasound does not adapt to the development trend of clinical informatization and restricts the further clinical application of ultrasound in ICUs.

1.3 Current Industry Status

At present, solutions are designed to integrate bedside ultrasound image information with clinical data. A widely used solution is to connect the electrode pad on the body to the built-in ECG module of ultrasound equipment during echocardiographic examination so that ultrasound images and ECG signals can be acquired simultaneously. However, this operation requires the physician to disconnect the patient-connected lead wire from the patient monitor, which is time-consuming and laborious. This makes it impossible to acquire physiological signals other than ECG signals. Another solution is to send ultrasound images to the department's information system by installing a video acquisition card on ultrasound equipment. In this solution, the operations are more complicated and time-consuming, and the quality of ultrasound images is affected by image compression, making it difficult to ensure time synchronization between ultrasound images and clinical data. This significantly reduces the clinical value.

The preceding solutions solve a specific type of problems from a single dimension, without providing strategies in terms of clinical scenario and system.

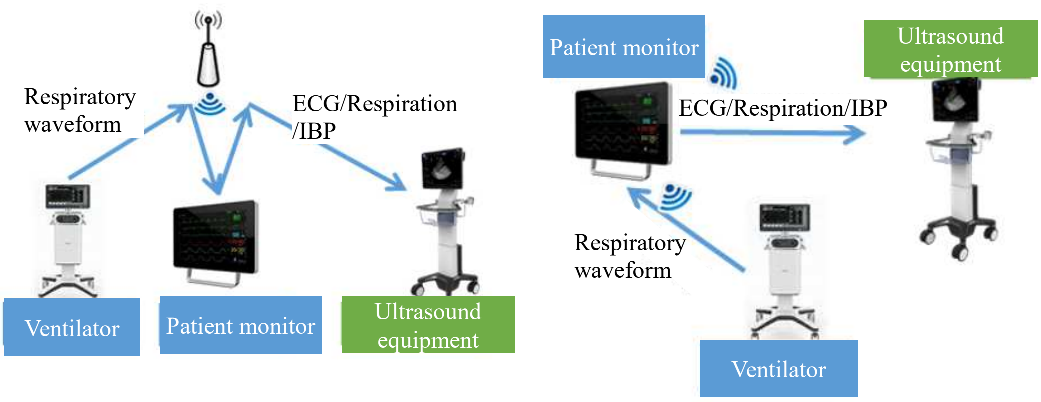
2 Technical Solution

X-Link implements wireless connection and data exchange among the ultrasound equipment, patient monitor, and CMS for the first time by using IT and data synchronization technology. The integration of ultrasound equipment into the ICU bedside information network is an integral part of the bedside monitoring and diagnosis system.

With the wireless network provided by the ICU or the Wi-Fi hotspot provided by the patient monitor, the patient monitor establishes a connection to ultrasound equipment through the wireless network and sends monitor parameters and patient information to the ultrasound equipment. If the patient monitor has established a connection to the ventilator, the patient monitor also sends ventilator parameters to the ultrasound equipment.

Scenario 1: A wireless network is provided by the department

Scenario 2: No Wi-Fi is provided by the department and the patient monitor is used as a Wi-Fi hotspot



Through the Wi-Fi provided by the department, the ventilator sends the data to the patient monitor, which then sends the data to the ultrasound equipment.

1. The patient monitor provides a Wi-Fi hotspot and is connected to the ultrasound equipment.

2. The patient monitor sends its ECG/IBP waveforms and the respiratory waveforms of the ventilator to the ultrasound equipment.

Figure 1 Monitor parameters sent to the ultrasound equipment

If a CMS is equipped in the ICU and a wireless network is provided, the ultrasound equipment directly sends ultrasound images to the CMS. If the patient monitor provides a Wi-Fi hotspot, the patient monitor can function as a transfer workstation for sending ultrasound images to the CMS.

Scenario 1: A wireless network is provided by the department

Scenario 2: No Wi-Fi is provided by the department and the patient monitor is used as a Wi-Fi hotspot

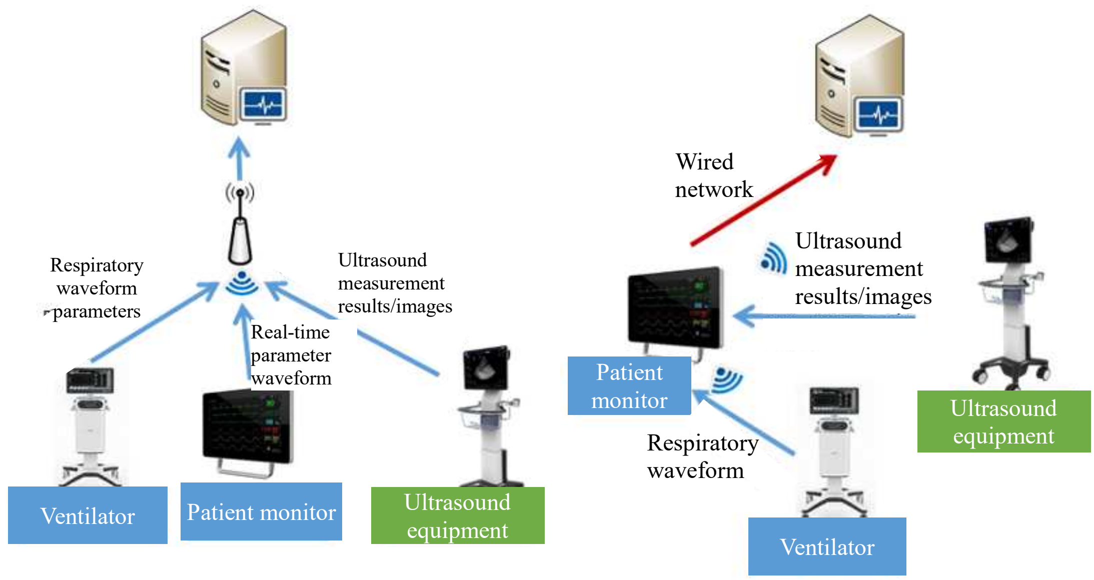


Figure 2 Ultrasound images sent to the CMS

The preceding two forms of information transmission can be implemented through the following two applications: Physio-View running on the ultrasound equipment and U-View running on Mindray CMS.

2.1 Physio-View

It establishes a network connection to the patient monitor, acquires patient monitor parameters and patient information, and displays the information on the ultrasound image screen. When a physician performs an ultrasound examination on the bedside, the physician can quickly obtain patient information by selecting the bed number and then create a new examination record in one click. During the ultrasound examination, the physician can select patient monitor parameters, which are displayed on the screen in real time. It is convenient for the physician to observe the ultrasound image and patient monitor parameters at the same time. For example, ECG parameters are used for echocardiographic examination, or ventilator pressure parameters are used for inferior vena cava ultrasound examination to improve the efficiency of clinical analysis.

At the end of the ultrasound examination (or saving the image or movie), Physio-View sends ultrasound images to the CMS.

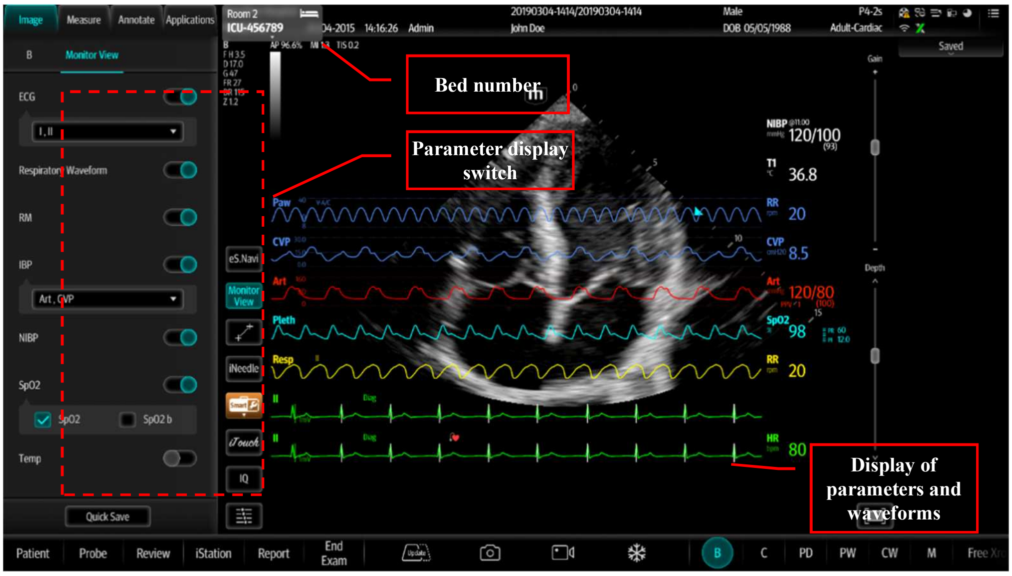


Figure 3 Home screen of Physio-View

Table 1 Parameter types supported by Physio-View

Type	Data	Description
ECG (electrocardiograph)	Up to two ECG waveforms, and HR	Measurement calibration and comprehensive decision-making of cardiac functions
Resp (respiration)	Respiratory waveform and RR	Measurement calibration and comprehensive decision-making of respiratory functions
SpO2 (pulse oxygen saturation)	Up to two Pleth waveforms, SpO2, PR, and PI	Comprehensive hemodynamic decision-making, such as CPR quality
NIBP (noninvasive blood pressure)	Systolic pressure, diastolic pressure, and mean pressure	Comprehensive hemodynamic decision-making, such as shock diagnosis
IBP (invasive blood pressure)	Up to four IBP waveforms, parameter values, and PPV	Comprehensive hemodynamic decision-making, such as shock diagnosis
CO2 parameter	CO2 waveform and RR	Comprehensive hemodynamic decision-making
Temp (temperature)	Up to one temperature value	
Respiratory mechanics parameter (from the ventilator or RM module of the patient monitor)	Paw waveform, Vol waveform, Flow waveform, RR, and ventilation mode	Measurement calibration and comprehensive decision-making of respiratory functions

2.2 U-View

Under the premise that Physio-View is set up and that the bed number is selected correctly, U-View can receive ultrasound images and display them on the CMS. By default, ultrasound images are displayed in the form of events. When a physician clicks the ultrasound event, U-View pops up the ultrasound browsing screen, displaying the ultrasound images, movies, and measurement results sent from Physio-View. In addition, the patient monitor parameters at the corresponding time are displayed next to the time axis of the ultrasound event. It is convenient for the physician to view the patient's ultrasound examination results at the CMS while browsing the patient monitor parameters such as HR, blood pressure, and SpO2 at the corresponding time for comprehensive analysis.

By referring to the patient's physiological information displayed by time axis on the CMS, U-View supports cross-examination browsing of ultrasound images. For example, if a patient is hospitalized in the ICU for a week, the corresponding bed number is selected through Physio-View during daily ultrasound examination, and ultrasound images, movies, or measurement results are saved. The physician can browse all ultrasound examination results of the patient during the week on U-View by time axis. This helps the physician quickly analyze the patient's physiological status and disease development trends based on dynamic ultrasound examination. On this basis, U-View can generate trend curves for measurement results, allowing the physician to compare and observe the increase in cardiac output before and after rehydration, the trend of changes in the number of lung B-lines during ventilation management, and the level of improvement in cardiac function during shock treatment in a more intuitive manner.

In addition to the display of all ultrasound examination results of a patient by time axis, U-View can also display ultrasound examination results by body parts. That is, according to the examination mode selected by the physician during ultrasound examination, U-View places the ultrasound image of the examination mode in the corresponding position of the body diagram, so that the overview of the ultrasound examination results is clear at a glance.

In general, U-View provides a convenient and intuitive bedside data tool that integrates ultrasound images. It matches the comprehensive and dynamic clinical thinking of ICU physicians and meets the needs of clinical condition analysis, diagnosis and treatment decision-making, and big data research.

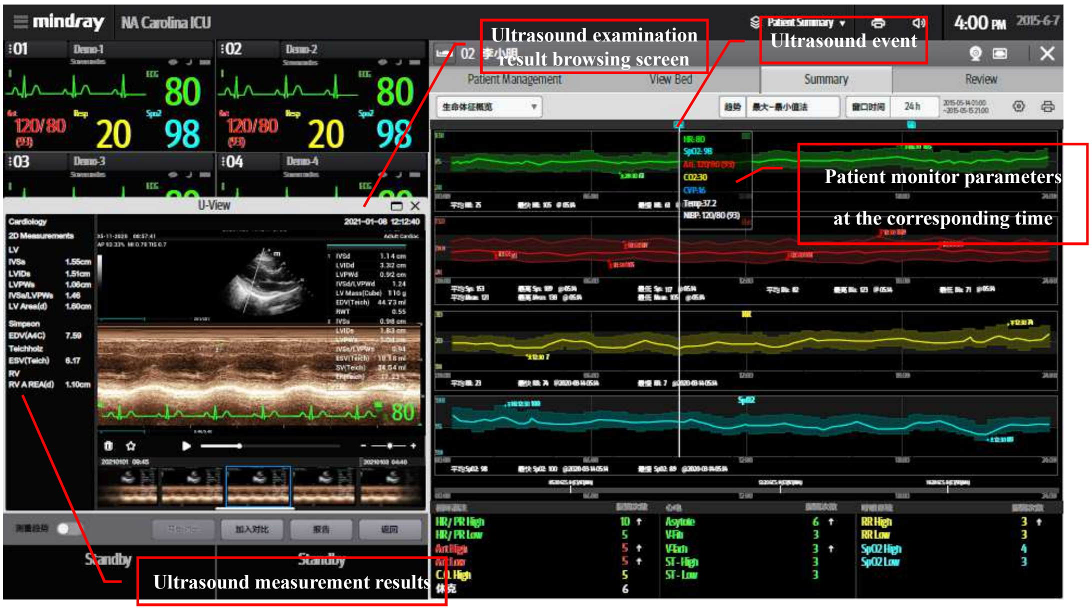


Figure 4 Home screen of U-View

Figure 5 Ultrasound examination result browsing screen supporting measurement result trend curves

Figure 6 Ultrasound examination result browsing screen supporting thumbnail browsing

3 Clinical Value

3.1 Multi-dimensional Comprehensive Decision-making

In the case of sudden low tissue perfusion, ICU physicians need to quickly analyze the cause of shock based on information such as vital signs, monitor parameters, lab analysis indicators, and medical history, and make diagnosis and treatment decisions. As a non-invasive and efficient visualization tool, ultrasound can supplement key information for physicians, helping physicians build systematic thinking and improve the efficiency of diagnosis and treatment. Based on information from ultrasound and patient monitors, physicians can rapidly make non-invasive diagnosis of shock.

Studies have shown that cardiac ultrasound is one of the most convenient tools for diagnosing the types of shock [1]. In addition to cardiac ultrasound examination, ultrasound is also used to monitor arterial catheters and central venous catheters. When a patient does not respond to the initial treatment or the case is complicated, other monitoring methods are recommended. In this situation, pulmonary artery catheters and transpulmonary thermodilution techniques can be the first choice. Therefore, physicians should integrate various indicators into the decision-making and management processes and formulate treatment schemes accordingly. The literature [2] mentions as follows: Distributive shock is usually characterized by an elevated cardiac output (CO), while the other types of shock are associated with low cardiac output. Hypovolemic shock is associated with low blood pressures and volumes, while these are increased in cardiogenic shock. Obstructive shock is associated with increased pulmonary artery pressure and dilated right-sided cavities. In the preceding decision-making process, blood pressure information is acquired through the patient monitor, while volume information can be quickly acquired through ultrasound.

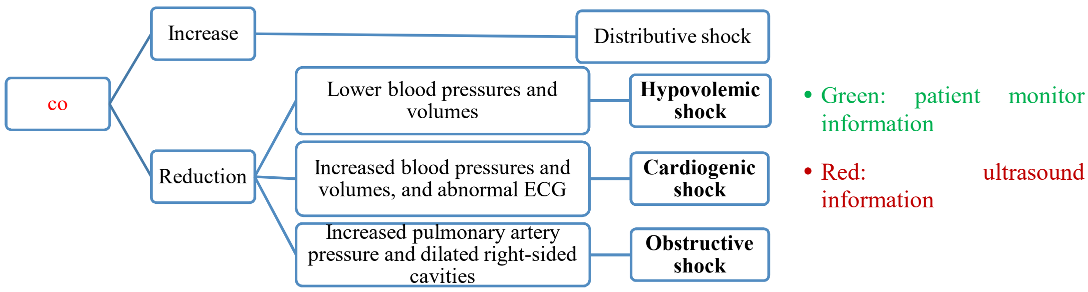


Figure 7 Diagnosis of shock based on information from the ultrasound equipment and patient monitor

3.2 Auxiliary Analysis by Phase

Critically ill patients often have high or low fluid volumes, such as tissue edema and low tissue perfusion due to vascular regulation dysfunction and poor cardiac stock capacity. In response to this situation, it is necessary to carry out volume management for critically ill patients. The evaluation of volume status and volume responsiveness is key to volume management.

The vena cava is the closest reflux vessel to the right atrium, which can better reflect the function of the right heart and the interaction between heart and lungs. As long as the right heart pressure changes, the inner diameter of the vena cava will change. Clinically, the inferior vena cava (IVC) is often used to evaluate the volume status and volume reactivity [3,4]. Through the acoustic window of the liver under the xiphoid, the opening of the hepatic vein into the IVC and the opening of the IVC into the right atrium (the IVC long-axis plane under the xiphoid) can be seen, and the change of the inner diameter of the IVC with the respiratory cycle can be observed. For a spontaneously breathing patient, the intrathoracic pressure during inspiration is negative pressure, so the inner diameter of the IVC collapses during inspiration. For a mechanically ventilated patient, the intrathoracic pressure during inspiration is positive pressure, so the inner diameter of the IVC reaches the maximum during inspiration while it reaches the minimum during expiration (Figure 2[5]). The phase of the ventilator parameter waveform assists with the analysis of the IVC inner diameter changes, so as to further evaluate the volume responsiveness.

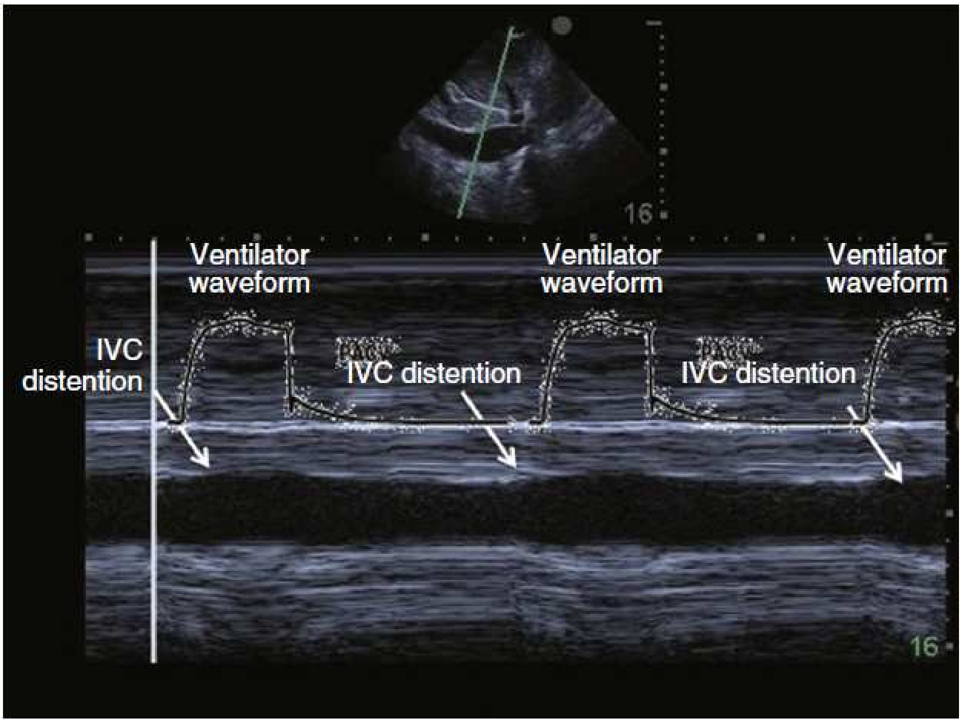


Figure 8 Predicting volume responsiveness through IVC breathing variation under mechanical ventilation (the black waveform indicates the PAW waveform of the ventilator)

Currently, it is not clinically possible to synchronously display the ventilator parameter waveforms on the ultrasound equipment. Therefore, when a physician combines the IVC ultrasound image and the breathing status to analyze the volume reactivity, the ultrasound image and the ventilator parameter waveform need to be exported to the computer for offline analysis.

In another aspect, the heart is the most frequently used part in ICU ultrasound examination. According to the American Society of Echocardiography (ASE) guidelines [6], it is important to acquire high-quality ECG signals when a physician determines the measurement time of echocardiography. Since these signals can trigger video capture, good "R" and "T" waves are crucial for digital image capture.

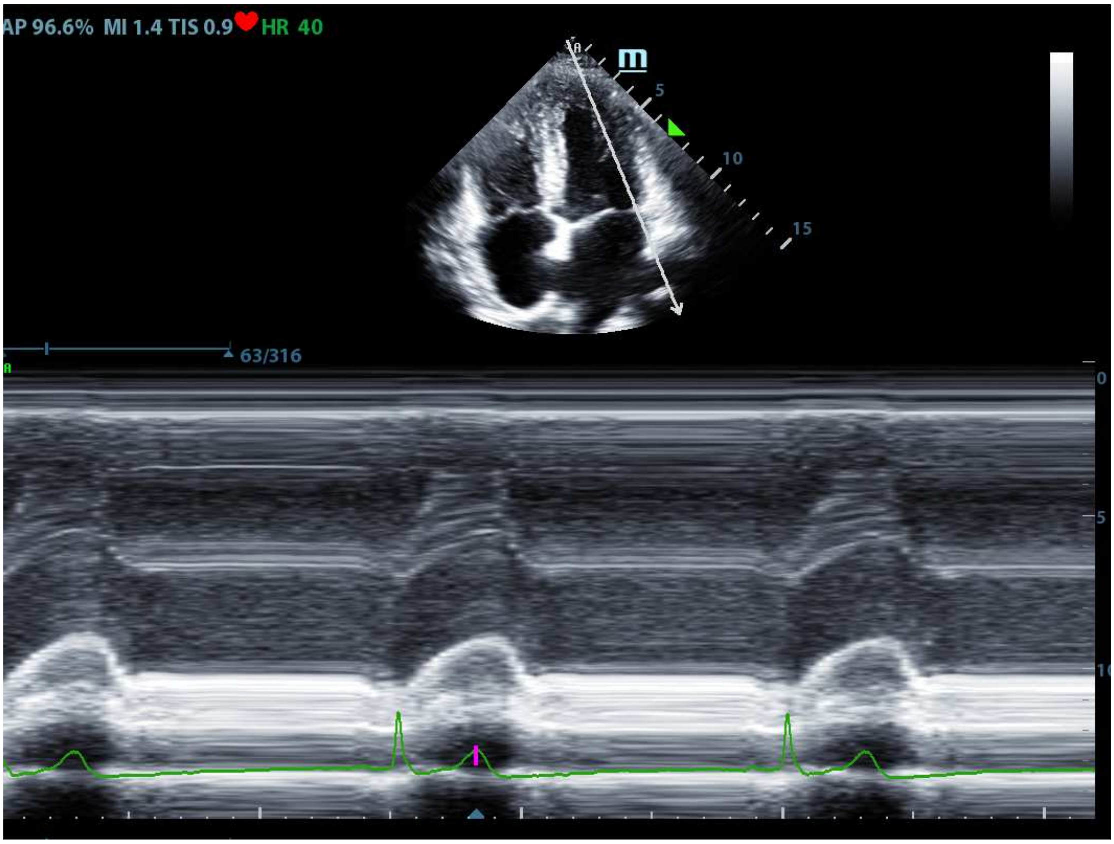


Figure 9 ECG-assisted echocardiographic analysis

In ICU situations, the patient is generally already undergoing ECG with the patient monitor. For example, when the ECG signal is connected during an echocardiographic examination, it is necessary to remove the cable of the electrode pad on the patient and replace it with the ECG cable of the ultrasound equipment. It is cumbersome to operate and is not conducive to continuous monitoring by the patient monitor. Therefore, the ECG signals are often not connected during echocardiographic examination in ICUs, which adversely affects the accuracy and efficiency of bedside cardiac ultrasound examination.

3.3 Big Data for Clinical Research

A large number of monitoring systems configured in the ICU continuously collect the patient's breathing, hemodynamics, and other data. It is difficult and time-consuming to analyze high-granularity and massive data using traditional statistical analysis methods. In addition, it is also impossible for clinicians to find key features in a large amount of data in real-time to make accurate diagnosis and treatment decisions. The development and application of artificial intelligence (AI) technology is breaking this pain point. AI algorithms have big data analysis and processing capabilities. After an algorithm model is trained, it can mine the key features of the data generated in the application environment, and quickly calculate the information and knowledge required for clinical diagnosis and treatment decisions. The big data generated by the ICU in the process of continuous monitoring of the patient provides the basis for the training and application of algorithm models. The application and evaluation of algorithm models have also become an emerging direction of ICU clinical research.

In addition, with the popularity of ultrasound in ICUs, clinicians are paying more attention to big data research that incorporates ultrasound images. For example, cardiac blood flow ultrasound and blood pressure can be combined to evaluate the end-systolic pressure-volume relation of the ventricle [7]. Since the cardiovascular system is a unified whole, the arterial load and its vascular elasticity will affect the functional status of the left ventricle, and vice versa, and the function of the left ventricle will also change the arterial characteristics. The interaction between the two is the end-systolic pressure-volume relation, which is an important indicator reflecting the efficiency of ventricular work and energy transfer.

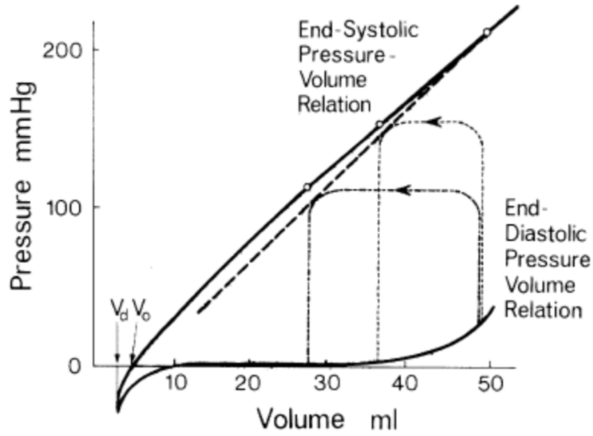


FIGURE 1. *Schematic diagram for end-systolic pressure-volume relation and its parameters V_0 and V_d. See text for definitions. Three open circles on the solid line represent three isovolumic peak pressures. The broken line represents the end-systolic pressure-volume relation line obtained from two ejecting contraction loops as opposed to the isovolumic pressure-volume relation line.*

Figure 10 Evaluation of the heart-vascular coupling through the left ventricular volume-pressure curve

In the fields of ventilation and weaning strategies of the ventilator, there are also clinical scientific researches on comprehensive ventilator parameters, monitor parameters, and ultrasound measurement indicators. However, the target clinic lacks a data platform that can conveniently acquire ultrasound images, which restricts the development of clinical big data research.

4 Case Study

4.1 Case History

A patient was hospitalized for chest tightness more than three years ago and was diagnosed with dilated cardiomyopathy. The patient was discharged after improvement.

For more than three years, the patient regularly took Entresto to treat heart failure, Betaloc to improve ventricular remodeling, and torasemide and spironolactone to promote diuresis.

One week before hospital, the patient developed oliguria, active chest tightness, and shortness of breath, and was initially diagnosed with dilated cardiomyopathy, chronic heart failure, and valvular heart disease.

4.2 Examination Upon Admission

The patient experiences aggravated chest tightness and shortness of breath, as well as dizziness, fatigue, and dyspnea while sitting. While sedated by drugs, the patient's bilateral pupils are equicircle, about 3 mm in diameter, and slowly reactive to direct light. With tracheal intubation in place, many moist rales are recorded during auscultation of both lungs. The patient's abdomen is soft, with non-cooperative tenderness pain and rebound tenderness. The patient's muscle strength of limbs is non-cooperative, with negative Pap test results.

The patient's skin is spotted, wet, and cold. The monitor parameters are as follows: fast heart rate reaching 120–140 BPM; low blood pressure, 76/50 mmHg; respiratory rate 10–12 BPM; low oxygen saturation, 95%. Blood gas analysis shows that the lactic acid level increases progressively.

Based the preceding vital signs and various parameters, the patient is clinically diagnosed with shock. The type of shock must be determined as soon as possible.

4.3 Ultrasound Cardiac Examination

Firstly, evaluate the systolic function of the heart, and the LV EF is 28.68%, indicating left ventricular systolic insufficiency. Then, evaluate the diastolic function and measure E\A and E\e' by ultrasound. The process is as follows: Enter tissue velocity Doppler (TVD) to observe the peak of early diastolic velocity E' and the peak of late diastolic velocity A' of mitral valve annulus, to find that the patient's diastolic function is seriously abnormal, which is not a normal double-peak performance. The clinician cannot accurately distinguish E' peak from A' peak. Through X-Link, the clinician can quickly acquire the simultaneous ECG waveform on the ultrasound screen after entering Physio-View. After comparing the ECG waveform with the TVD waveform, based on the physiological law of T wave and E' peak, the clinician can clearly distinguish E' peak from A' peak and complete the measurement. Severe diastolic dysfunction is found.

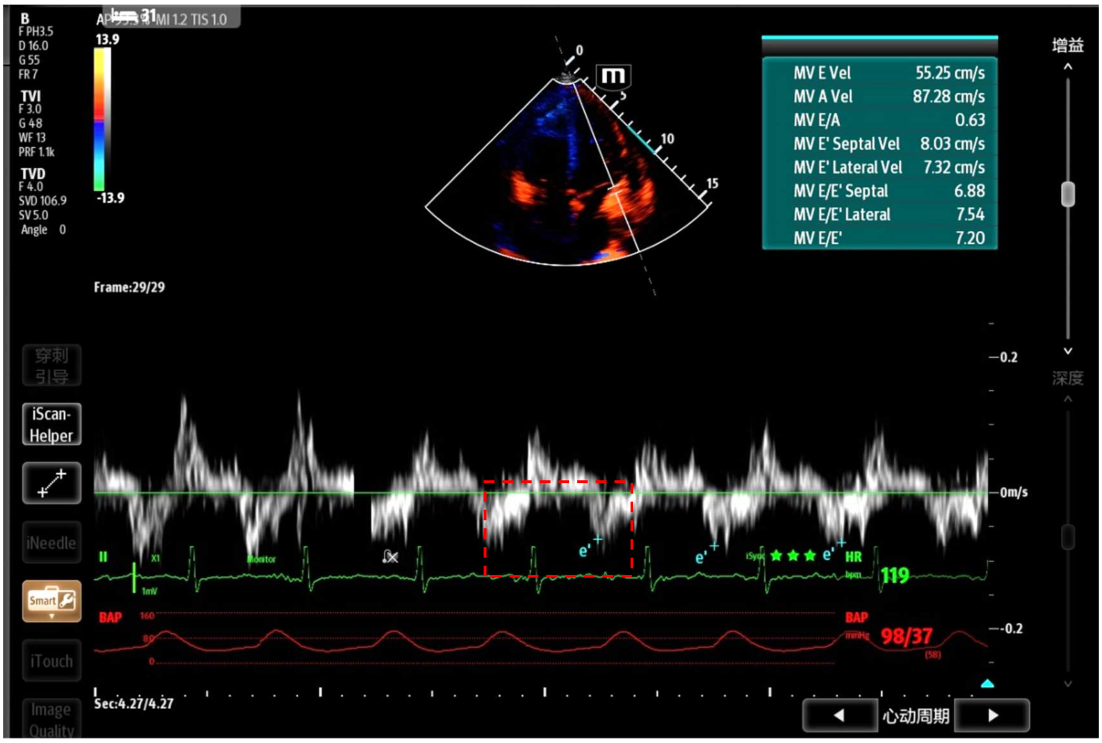


Figure 11 E' peak measurement under TVD to determine the position of E' peak through the ECG waveform.

After the preceding analysis, the patient is diagnosed with cardiogenic shock and needs V-A ECMO support.

4.4 Ultrasound-guided Catheterization

In the process of ECMO, it is necessary to closely monitor the hemodynamic status so that a Swan-Ganz catheter can be placed under the guidance of ultrasound. Pulmonary artery (PA) pressure should be monitored during catheterization: When the catheter reaches different parts, the patient's blood pressure shows corresponding characteristics, so the change of blood pressure can help to judge whether the catheter path meets the expectation. X-Link directly displays the vital sign information (such as blood pressure and heart rate) of the patient monitor in the ultrasound image area, so that the clinician only needs to focus on the ultrasound screen, while observing the catheter position in the ultrasound image and the PA curve. This ensures safe and smooth completion of catheterization.

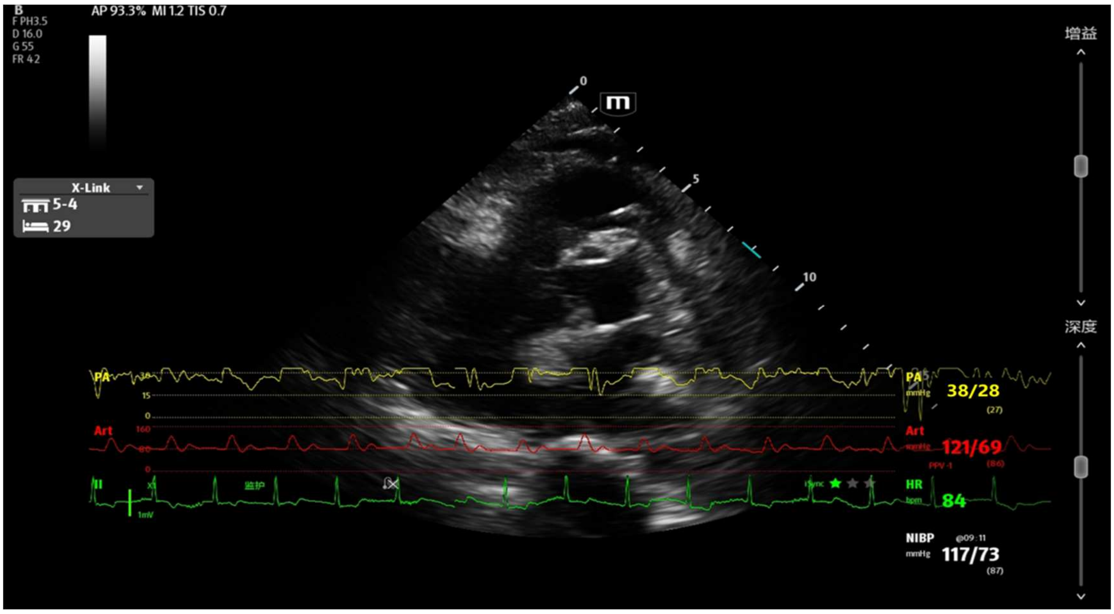


Figure 12 Catheter reaching the right atrium

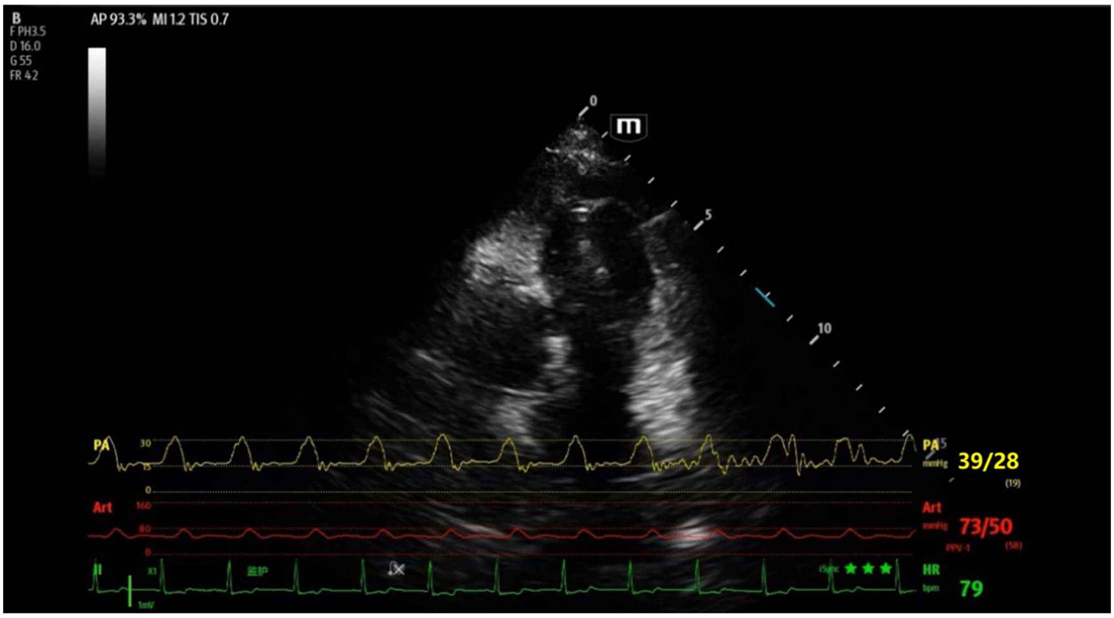


Figure 13 Catheter reaching the pulmonary artery

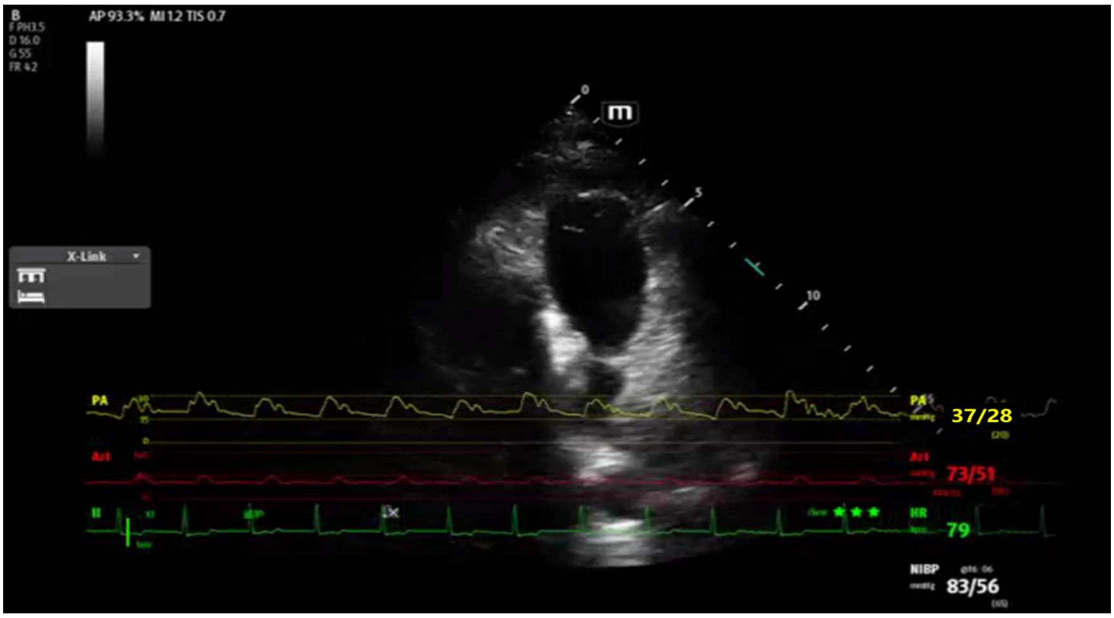


Figure 14 Catheter reaching the distal end of pulmonary artery stenosis

After ECMO is connected, pay close attention to the volume status and formulate a fluid management plan.

4.5 Dynamic Evaluation of the Volume Status

The relevant parameters derived from ultrasonic examination are as follows: IVC variation rate – 76% (obvious variation), indicating volume reactivity; B-line not found in lung ultrasonography; VTI – 9.66 cm. Combined with physiological indexes: HR – 118 bpm; BP – 80/51 mmHg; CVP – 4.7 mmHg; CRT – 4s. It is judged that the perfusion status of the patient is not good, with insufficient volume. The patient must be rehydrated immediately.

After 6 hours of rehydration, the results of ultrasound examination show that the IVC variation rate is 36%, suggesting that there is still volume reactivity; VTI is 10.18 cm, indicating an increase in cardiac output; B-line is not found in lung ultrasonography, indicating a safe state. Combined with the physiological index CVP, which is 5.7 mmHg, it is judged that there is volume reactivity. Based on comprehensive judgment, rehydration can continue.

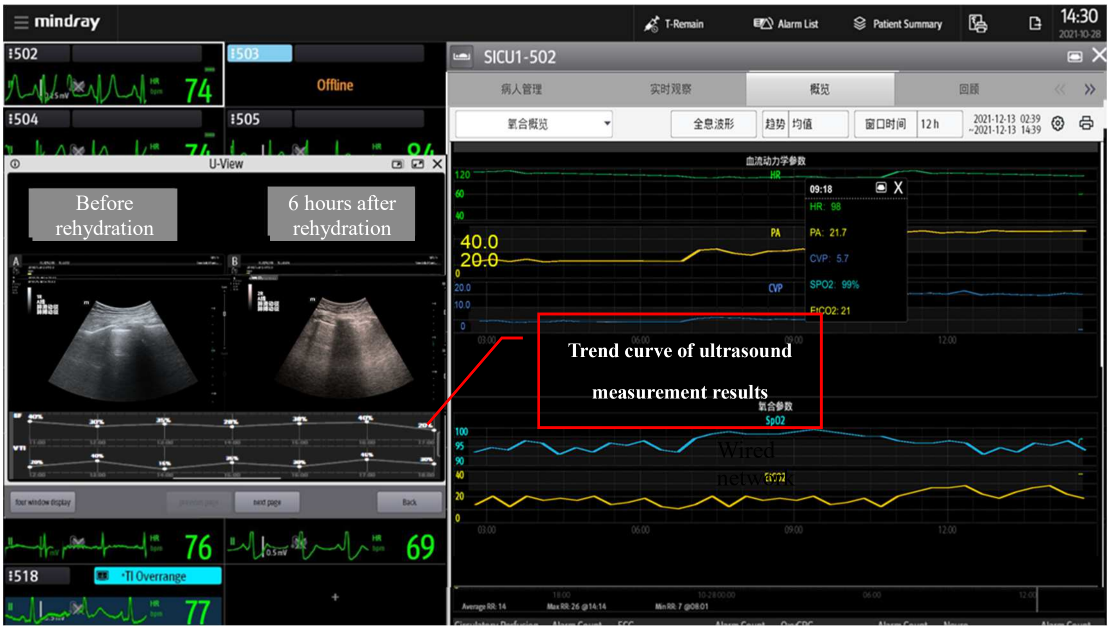


Figure 15 U-View screen after 6 hours of rehydration

After 12 hours of rehydration, the results of ultrasound examination show that the IVC variation rate is 4%, suggesting that there is no volume reactivity; VTI is 13.52 cm, indicating an increase in cardiac output; B-line is found in lung ultrasonography, indicating extravascular lung water. Combined with the physiological index CVP, which is 16.7 mmHg, it is judged that there is no volume reactivity but there is a risk of volume overload. Based on comprehensive judgment, rehydration is stopped.

Figure 16 U-View screen after 12 hours of rehydration

The ultrasound images and measurement results of the preceding processes can be conveniently sent to the CMS through X-Link and displayed on U-View. This allows the clinician to observe the physiological information of the patient monitor and the ultrasound images at the same time, as well as the corresponding change curves, so that the clinician can evaluate the development trend of the patient's physiological status to conduct multi-dimensional and systematic analysis.

	Before rehydration	6 hours after rehydration	12 hours after rehydration
Lung ultrasound	**A-line**	**A-line**	**Many B-lines**
IVC variation rate	76%	36%	4%
VTI	9.66cm	10.18cm	13.52cm
HR	118	98	108
PA	15.7	21.7	30.7
CVP	4.7	5.7	16.7
SPO2	95%	99%	95%
EtCO2	34	31	31

Figure 17 Trend curves of comprehensive ultrasound measured values and physiological parameters of the patient monitor

5 Conclusion

X-Link ultrasound-monitoring interconnection technology realizes wireless connection and data exchange among the ultrasound equipment, patient monitor, ventilator, and CMS, helping physicians acquire patient information and create examination in one click through standardized operations. Physicians can observe the waveforms of examination-related physiological parameters (such as ECG) on the same screen during ultrasound examination, which assists with ultrasound analysis and measurement to improve the accuracy of ultrasound examination. Physicians can also view physiological parameters and ultrasound images on the CMS at the same time, so as to meet the clinical needs of comprehensive analysis and dynamic management. Finally, X-Link provides a convenient bedside data platform with ultrasound image display, laying a reliable basis for ICU information management and academic research.

6 References

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